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FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

OPEN MEETING

REEVALUATION OF THE HUMAN HEALTH EFFECTS
OF ATRAZINE:

REVIEW OF NON-CANCER EFFECTS AND
DRINKING WATER MONITORING FREQUENCY

DOCKET NUMBER: EPA-HQ-OPP-2010-0481

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY

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SEPTEMBER 17, 2010

8:35 A.M.

FIFRA SCIENTIFIC ADVISORY PANEL

MEETING

SEPTEMBER17, 2010

DR. STEVEN HEERINGA: Good morning, everyone, and welcome back to this fourth and final day of the FIFRA Scientific Advisory Panel Meeting on the topic of the Re-Evaluation of the Human Health Effects of Atrazine: Review of Non-Cancer Effects and Drinking Water Monitoring Frequency.

I think since there are very few new faces in this room that we won't go around and have the Panel introduce themselves this morning. I'll just say I'm, I'm Steve Heeringa. I'm the Chair of the proceedings.

I want to thank Dr. Portier for filling in for me late yesterday afternoon, and I understand that we have gone through the Charge Question No. 4 and its subparts. Dr. Portier has left it open for any additional comments from Panel Members related to Charge Question No. 4.

Any additional thoughts overnight from people, things they would like to add on the of course, until the end of these proceedings if something comes to mind, you're always welcome to bring it forward. So don't hesitate, but in terms of sort of



1 the organization of our discussion, nothing else to
2 add? Wes, Dr. Coupe, others all set? Thank you.

3 **SPEAKER:** You're okay?

4 **DR. STEVEN HEERINGA:** Okay. Well, if
5 that is the case, I want to turn briefly to Joe Bailey,
6 the Designated Federal Official for these meetings,
7 just to see if Joe has anything to add before we begin.

8 **DR. JOSEPH BAILEY:** I really don't have
9 anything to add, I just want to welcome everybody back
10 for the last day. I think we've made good progress on
11 the agenda so far. We're right on target, if not a
12 little bit ahead, so .

13 **DR. STEVEN HEERINGA:** Do you want to
14 mention hydroxyatrazine?

15 **DR. JOSEPH BAILEY:** Oh, yes, I will make
16 one comment. Dr. Stone yesterday, I'm sorry, Mr.
17 Stone yesterday in the discussions about the water
18 issues made a reference to two USGS documents that
19 have some information on hydroxyatrazine monitoring.
20 He's going to provide me those references and the link,
21 and I will send that out to the Panel.

22 I believe Syngenta has also provided a
23 little bit of information, which I will also provide to
24 the Panel. It did come in after the Comment period had
25 closed, so I will treat that accordingly and send it to



1 you as well and put it in the docket. That's all I
2 have.

3 **SPEAKER:** Last night I downloaded the
4 most recent JNPR evaluation of atrazine and all of its
5 metabolites, so I can provide that reference and the
6 link as well.

7 **DR. STEVEN HEERINGA:** Thank you very
8 much.

9 **DR. JOSEPH BAILEY:** Okay, good. Thank
10 you.

11 **DR. STEVEN HEERINGA:** That's very good.
12 So those materials will all be available to the Panel
13 on the docket, and I think several of these things are
14 in hard copy.

15 **DR. JOSEPH BAILEY:** It will all be
16 electronic.

17 **DR. STEVEN HEERINGA:** Okay, thank you
18 very much.

19 Okay. At this point, just to give
20 everybody a sense of what I would anticipate for the
21 day, it is my intent to finish by 12:00, and that gives
22 us well over three hours of total time on two questions
23 and wrap-up, and we should be able to do that. So
24 that's. again, I, if it turns out that we have
25 productive discussions that take us longer we'll do



1 that, but that's my aim. People are trying to plan
2 their day here.

3 At this point in time, I think I'll turn
4 to maybe Nelson to read the Charge Question No. 5 into
5 the record or

6 **DR. JACK FOWLE:** I want to introduce
7 myself, my name is Jack Fowle, and I'm the Deputy
8 Director of the Health Effects Division in the Office
9 of Pesticides.

10 **DR. STEVEN HEERINGA:** Okay.

11 **DR. JACK FOWLE:** And it clearly must be
12 an atrazine SAP, because Anna has written saying there
13 is a major water-main break and she's got to take a
14 major detour.

15 **SPEAKER:** Oh, again?

16 **DR. JACK FOWLE:** So she will be a little
17 bit late, so we'll proceed.

18 **DR. STEVEN HEERINGA:** What was it, a
19 snowstorm last

20 **SPEAKER:** I think it was another water
21 main.

22 **DR. STEVEN HEERINGA:** A water main,
23 okay.

24 **DR. JACK FOWLE:** Something like that.

25 **SPEAKER:** Was there an accident at some



1 point in time?

2 **DR. STEVEN HEERINGA:** Okay. Well, thank
3 you very much.

4 **DR. JACK FOWLE:** If you can put up with
5 my scratchy voice, I can read this question, Question
6 5: The Agency requests the Panel to comment on
7 important scientific factors for the Agency to consider
8 in its analysis.

9 Please include in your comments specific
10 consideration of uncertainties in estimating drinking
11 water exposures and remaining uncertainties in
12 atrazine's toxicological profile across life stages,
13 particularly as they pertain to assessing risk to
14 infants and children.

15 **DR. STEVEN HEERINGA:** Our first...thank
16 you very much first, Dr. Fowle.

17 I want to turn to our lead discussant on
18 this, Dr. Pope.

19 **DR. CAREY POPE:** Yes, good morning. So
20 Question 5, I saw two parts of it, basically asking
21 about uncertainties regarding drinking water exposures
22 for young individuals and uncertainties in the
23 toxicological profile across life stages.

24 I don't have a whole lot to say about
25 the first aspect, although I did pick up a couple of



1 things that I would consider that evaluating treated
2 water samples for levels seems a better approach than
3 untreated water sources.

4 The other question about the duration of
5 dosing, it would be better you know, currently,
6 there's a 90-day rolling average in whether there may
7 be a better duration of exposure to use. I'm still not
8 certain whether there's in my mind a better duration to
9 point to for either the adults or the developing
10 individuals.

11 Regarding the second part of this
12 question about the profile across life stages, I have a
13 little bit more to say.

14 And by the way, Dr. Meek is not here;
15 but she provided her information to me, and I have that
16 as well.

17 **DR. STEVEN HEERINGA:** Yeah, she said she
18 would do that. That's very good.

19 **DR. CAREY POPE:** So while there is a
20 good consensus about atrazine's influence on GnRH-
21 mediated LH surge and the reproductive or developmental
22 toxicity, there is also some confusion, as would be
23 expected. The Morseth, et al., study, currently used
24 to set the point of departure, has not been replicated
25 in more recent studies from the registrant using



1 relatively similar dosing strategies, repeated dosing,
2 dietary. And, you know, in the review, it's difficult
3 to reconcile some of these differences in these
4 studies.

5 In the studies using radiolabeled
6 atrazine, it appeared to me that, if anything, there
7 was less uptake of atrazine across a placenta than
8 levels noted in the dam, and these suggest that there
9 may not be selectively higher exposures to the
10 developmental organism during prenatal period.

11 A number of studies examined relative
12 toxicity with either prenatal dosing, postnatal or
13 peripubertal exposures to atrazine. And with the
14 prenatal exposures, generally endpoints like preputial
15 separation and mammary gland development were noted;
16 but the repeated exposures were somewhere between 50
17 and 100 milligrams per kilogram per day. And prenatal
18 combined with lactational exposures showed similar
19 effects on preputial separation and prostatitis; but
20 only 100 milligrams per kilogram per day were used.

21 Several studies evaluated the effects
22 during peripubertal exposures, and again preputial
23 separation was affected. And this, from what I could
24 see, was the lowest dose where you saw a developmental
25 effect, and it was at 12.5 milligrams per kilogram per



1 day for quite an extended period.

2 Testosterone levels were evaluated with
3 a couple of studies, and I think the lowest dose,
4 effective dose, was 50 milligrams per kilogram per day.

5 Thus, in this collection of studies,
6 there's not much evidence that either prenatal,
7 lactational or peripubertal exposures were leading to a
8 higher sensitivity in development of organisms.

9 We spent quite a bit of time yesterday
10 on a number of occasions talking about the studies with
11 the atrazine mixture by Enoch, et al., on 2007.

12 And also the hydroxyatrazine metabolite
13 has come up a number of times. I want to say here that
14 all hydroxyatrazine metabolites are not created
15 equally. There is a ring structure hydroxylation,
16 which appears to be the one used in Enoch's paper that
17 appears to be an environmental contaminant, and the one
18 set are reported in the metabolism studies for alkyl
19 hydroxylations, including a recent paper by, from
20 Hotchkins Lab showing ethyl and isopropyl
21 hydroxylations.

22 And I'm not sure, Dr. Lowit mentioned
23 yesterday that there are some studies in the literature
24 looking at the hydroxyatrazine metabolite. I'm not
25 sure which ones she's referring to, whether they're the



1 ring hydroxylations or the alkyl hydroxylations. I
2 think it could be important.

3 But regardless, this paper reported
4 significant changes in mammary gland development with
5 very low levels, down to less than 1 milligram per
6 kilogram per day, with this atrazine mixture.

7 The white paper, one of the kind of
8 overall feelings I had as I went through the white
9 paper is that the study by Enoch and coworkers in 2007
10 was being kind of downgraded, so to speak, as far as
11 its potential influence in the risk-assessment process
12 for a number of reasons.

13 However, I feel that capturing the
14 makeup of water contaminants, it in my mind is a good
15 idea while it's obviously more complex to handle and
16 interpret.

17 There's obviously some legitimate
18 questions noted concerning the data in that paper.
19 We've already talked about the score and the
20 histological lesions and the reporting and the analysis
21 of the lesions, and whether they are histological or
22 morphometric is better.

23 There was obviously some low mean scores
24 in one of the control groups in that mammary
25 development data that kind of weakened the impact of



1 it.

2 There was little change in the effect
3 with the higher dosages across a hundredfold dose
4 range, which could be difficult to interpret; however,
5 I think it's also reasonable to assume that even if
6 results like that don't really fit very well into a
7 risk-assessment process and trying to determine points
8 of departure, I think it's reasonable to think that
9 some kind of developmental alteration could occur at a
10 certain level once a minimal level of exposure is
11 reached. It doesn't really matter if you can have more
12 added on top of it.

13 One interesting piece of information
14 that I haven't heard and didn't key into before this
15 morning when I was kind of looking over these papers
16 again was a paper by Stoker and Cooper in 2007 when
17 they looked at tissue distribution radioactivity
18 following C14 atrazine, and the mammary gland was
19 incredibly packed, relatively speaking, full of
20 atrazine or metabolites. It was the highest percent of
21 radioactivity, higher than liver and kidney; and I made
22 a graph of this, but I'm not sure there's really much
23 reason to show it.

24 **DR. STEVEN HEERINGA:** We can bring it
25 up. We'll bring it up if you went through all the



1 trouble to make a graph.

2 **DR. CAREY POPE:** Yeah, it wasn't that
3 much trouble.

4 So you can see that there's quite a
5 range of tissues here, including tissues from the
6 central nervous system, spleen, liver, kidney, gonads.
7 And, you know, to me, that's pretty striking that there
8 may be something to think about as far as accumulation
9 of atrazine or its metabolites in the mammary gland.
10 And this is the dam following oral dosing, 2 milligrams
11 per kilogram. I think it's 3 hours after dosing.

12 It's not the developing mammary gland;
13 but, you know, if it is, if that was the developing
14 mammary gland, you'd think, "Wow. Maybe putting these
15 two things together, there's something to it".

16 And thus while I think no other studies
17 aside from Enoch, et al., in 2007 have used this
18 mixture, it's a much more complicated thing to think
19 about as far as what these metabolites are, and I think
20 to me it kind of sends up a flag that the mammary gland
21 may be highly exposed and may be highly sensitive
22 during the development.

23 A little bit more about the
24 hydroxyatrazine ring structure hydroxyl group, it's
25 apparently a minimal component in the mammalian



1 metabolism or maybe not even a component of mammalian
2 metabolism of atrazine; but it appears to be a
3 substantial environmental contaminant.

4 I didn't, however, look at the original
5 papers that was cited in the Enoch, et al., that refers
6 back to the lowest concentrations of that in the water
7 samples.

8 So the very low exposure levels suggest
9 that the mammary gland effects may be sensitive
10 endpoints following gestational exposure to atrazine
11 and/or its metabolites. There is no clear-cut
12 mechanism for what might be happening. These findings
13 which apparently selected the accumulation of atrazine
14 or its metabolites in the mammary gland provide concern
15 for me that the high sensitivity is developing in
16 organisms.

17 And as noted yesterday, I mean, I think
18 standing alone, the Enoch, et al., paper is kind of, is
19 standing alone. There is not much to kind of reinforce
20 those findings, and so I think replication and
21 extension of those findings with dosimetry and looking
22 at individual effects on a mammary gland at low-level
23 exposures are, are necessary to effectively influence
24 the risk assessment.

25 **DR. STEVEN HEERINGA:** Thank you, Dr.



1 Pope.

2 And Dr. Chambers.

3 **DR. JANICE CHAMBERS:** Thank you. Just a
4 couple of things that I certainly agree with with what
5 Carey just said. I think the finished water will be a
6 better reflection of what the developing organism human
7 would be exposed to, and also the fact that an awful
8 lot of the data we saw were just on high doses is not
9 reflective of what humans would be exposed to. So we
10 certainly need more low-dose information.

11 I guess a couple of things that I keyed
12 into is with respect to the uncertainties you're
13 dealing with. I think you're doing, we're seeing a lot
14 more of the kinetic studies right now, and I think
15 those are extremely useful in trying to determine what
16 the internal dose of both the moms and the fetuses or
17 the pups would be, so I would encourage doing that.

18 The feeding regimens we were seeing, I
19 think it is a much more realistic paradigm for
20 presenting the delivery or delivering the dose as it
21 would be seen in drinking water exposures, and so I
22 would encourage more of that. It's not drinking water,
23 but it is an exposure that occurs over a period of time
24 as opposed to one bolus and a gavage dosing thing; so I
25 think that probably is useful.



1 The pseudo-steady state data that we saw
2 that was presented to us and everything was very, very
3 useful, I think, in trying to estimate what the
4 internal dose is, which hopefully can then be related
5 to the toxicology data.

6 Another thing that is going to be useful
7 I gather that's on the mill or in the works right now
8 is getting enough data to develop a PBK model, and that
9 would be useful. Certainly to get that appropriate for
10 the developing organism, we're going to need some
11 metabolic parameters on the developing organism fetus
12 and the infant child.

13 Some of the data we saw -- and I think
14 this was from Syngenta's metabolism parameters -- only
15 had one human sample. We're certainly going to need
16 more than one human to get a representative number on
17 that.

18 I guess one of the most equivocal things
19 we've talked about -- and we talked about it at length
20 yesterday and Carey just talked about it quite a bit
21 today -- was that mammary gland issue with the Enoch
22 paper. It's really hard to sort that out; I mean, you
23 struggled with it, and I agreed with your concern about
24 the conduct of that study. If it's real, it certainly
25 needs to be dealt with in risk assessment sooner or



1 later. I guess Gerry said yesterday we need to
2 determine whether it's an artifact or whether it's
3 real. So it certainly needs to be replicated so that
4 you can sort that out in, in the risk-assessment
5 process.

6 What you just presented with respect to
7 concentrations, that probably is not too surprising;
8 the mammary gland, I assume, would be a pretty lipid-
9 rich tissue and would accumulate lipophilic compounds.
10 So that's probably not too surprising; whether the fact
11 that it's there and the lipid is actually exerting any
12 toxic mechanisms is hard to know.

13 So, again, that's a big uncertainty that
14 I think we need to sort out. But it's out there, that
15 paper is out there at those low doses, and some sort of
16 replication needs to be done to determine how real that
17 is.

18 **DR. STEVEN HEERINGA:** Thank you, Dr.
19 Chambers.

20 Dr. Fenner-Crisp, Penny?

21 **DR. PENELOPE FENNER-CRISP:** A more
22 general statement, comment in addition to the ones that
23 the two have already made; I agree with theirs, as
24 well.

25 This is all about one aspect of the



1 decision-making process, well, not all about, but
2 incumbent in here is the decision on the 10x safety
3 factor. And embedded in that assessment process is
4 both a qualitative and a quantitative component.

5 The qualitative component being, do you
6 have data, and the appropriate data, that show whether,
7 what the toxicity profile at various life stages looks
8 like, and there's a lot of work going on to describe
9 that at various times.

10 But there is also a quantitative
11 component in here. Once you understand toxicity
12 profiles of various pre-adult stages, how do they
13 compare quantitatively with the adult? And I asked
14 Anna the other day if the Agency thought it had enough
15 data describing the toxicity profile in the adult
16 against which one could make comparisons, and she said
17 yes.

18 So I would submit that incumbent on the
19 Agency when they redo this discussion that that's where
20 you start. Here is what we have acquired in the adult
21 and it says such and so; here is what we've now done
22 with respect to various life stages.

23 The toxicity profiles match up or not,
24 as the case may be, and here are where quantitative
25 differences may exist, and therefore this would be our



1 decision logic for evaluating the component of the 10x
2 that's dedicated to the toxicology.

3 One of the things I found interesting
4 about the milk data was -- or that kinetic data was the
5 rough equivalence in plasma for the fetus and the
6 adult, but a significant drop-off in the milk.

7 So one can't understand fully what the
8 differential might be in sensitivity or tox profile
9 comparing with an adult there. I'm not suggesting you
10 go back and direct those pups with equivalent doses
11 that match the kinetics in the adult; but if it comes
12 to having to fully understand the kinetics in that life
13 stage, that's one thing that might be appealing.

14 I think at this stage, we can't comment
15 on whether or not the completed studies and those that
16 are in the pipeline are going to be sufficient to
17 answer all the questions on potential pre-adult
18 toxicity and the potential for quantitative
19 differences. So I think we have to, I would have to
20 reserve judgment on that until those studies are
21 finished.

22 **DR. STEVEN HEERINGA:** Thank you, Dr.
23 Fenner-Crisp.

24 Dr. Pope, could you read Dr. Meek's
25 comments into the record?



1 **DR. CAREY POPE:** Okay, this is from
2 Bette Meek, and I'll just have to read it word-for-
3 word: "Consideration of the value of the FQPA safety
4 factor is seemingly best predicated on transparent and
5 systematic consideration of the most important
6 qualitative and quantitative uncertainties associated
7 with both exposure and effect relevant to susceptible
8 life stages in a context consistent with that for other
9 pesticides.

10 In view of the fact that the database
11 for atrazine relevant to the selection of this factor
12 is still evolving, reference here is to some of the
13 generic aspects that might be explicitly considered
14 based on outcome of additional analysis, including for
15 exposure this could relate to the likelihood of
16 capturing the relevant periods of susceptibility or
17 over- or underestimating exposure for all life stages,
18 with the proposed monitoring strategy, including, for
19 example, consideration of determination of TCT rather
20 than atrazine.

21 "For effect, some critical questions
22 and/or aspects to be addressed in this context include:
23 to what extent does the database on hazard and kinetic
24 and dynamic data inform us about potential increased
25 susceptibility of infants and children?



1 Is the early key event or late adverse
2 effect for the critical effects sufficiently protective
3 for all age groups based on hazard characterization,
4 including knowledge of mode of action? How protective
5 is it, for example, an early key event protective for
6 later adverse effects?

7 What is the impact to the potential
8 reliance on a benchmark dose versus an effect level in
9 relation to uncertainty in the characterization of the
10 relevant dose-response relationship?

11 Does the degree of conservatism
12 associated with use of a lower confidence interval for
13 a benchmark dose increase confidence? And finally,
14 while the epidemiological data are not considered
15 sufficiently robust for inclusion in quantitative risk
16 assessment, can data from any of the studies that are
17 considered of highest quality be used to provide some
18 idea of relative sensitivity of various age groups of
19 the human population?"

20 **DR. STEVEN HEERINGA:** Thank you, Dr.
21 Pope. And again, those were Dr. Bette Meek's comments,
22 which she had written up and prepared for us.

23 At this point, I turn to the other
24 members of the Panel for any comments or additional
25 contributions on Charge Question No. 5?



1 Yes, Dr. McManaman?

2 **DR. JAMES McMANAMAN:** So in regards to
3 Dr. Chambers' statement that this would be a lipophilic
4 compound, it's unlikely to be lipophilic since it's
5 likely that those nitrogens are charged at
6 physiological pH and it has lots of hydrophilic
7 residues on it; so I think it's unlikely to be
8 lipophilic.

9 And if Dr. Pope could clarify the, that
10 the C14 distribution data, that was in a lactating dam?

11 **DR. CAREY POPE:** Yes.

12 **DR. JAMES McMANAMAN:** So during
13 lactation, there is very little adipose remaining in
14 the mammary gland; it's almost all been de-lipidated,
15 if you will, so it's almost all glandular structure.

16 Then regarding the risk assessment, it seems
17 to me that there are two underlying aspects of this.
18 Dr. Fenner-Crisp mentioned that there is qualitative
19 and quantitative.

20 And my concern is that we are trying to
21 - not "We are trying to do this", may be too strong --
22 but there is a move to try to put a square peg in a
23 round hole, in that if atrazine were directly
24 administered regarding the mammary gland, were directly
25 affecting the mammary gland, then that would be a



1 primary target and we could expect a normal dose-
2 response curve.

3 But if the mammary gland is a secondary
4 target related to some other aspect of physiology, then
5 I don't know that we would expect it to find a normal
6 dose-response curve.

7 And so my concern is that if it has to
8 have a dose-response curve to be considered as part of
9 the risk assessment, then I think that we're missing,
10 we potentially would be missing secondary effects of
11 which there may not be a normal dose-response curve.

12 Dr. Rayner's study showing that F2 pups
13 had lower weights in the atrazine-treated animals, this
14 suggests that it is a comp...atrazine is having complex
15 physiological effects that, again, would not expect to
16 be a simple dose-response curve, because F2 generation,
17 that's the grandchildren of the dam that was treated.
18 So I think that that needs to be taken into account in
19 assessing risk.

20 And if the models don't fit in a
21 preconceived notion, then I think that they should not
22 just be dismissed, and we should look for further
23 explanations in terms of risk assessment.

24 And then there is one other thing that I
25 want to have, make sure that it's read into the record,



1 and that is the Syngenta work, it's Figure 2 on Coder
2 D. I have it on my computer, but it's the Coder 2010 D
3 study, it's Figure 2.

4 And what it shows is it's the effect of
5 increasing doses of atrazine on the weights of dams
6 during lactation. And if we were to compare to the
7 pair-fed dam as the control as suggested by Syngenta
8 Group, then we have a dose-response relationship
9 between the 100milligram per kilogram atrazine and the
10 50 milligram per kilogram atrazine in terms of less
11 change in body weight. Okay? So the greatest change
12 in body weight was the pair-fed, and then the next was
13 100, and the next was 50.

14 So if that is, if we can use that as an
15 example, then I suggest that the Agency consider that
16 atrazine may be having metabolic effects and that's on
17 the adult, and I don't know that that -- it certainly
18 wasn't part of our Charge Question; but it's come out
19 of the data -- and that there be more studies related
20 to potential metabolic effects of atrazine on
21 particularly dams during lactation and possibly dams,
22 non-lactating dams and pups.

23 **DR. STEVEN HEERINGA:** Thank you, Dr.
24 McManaman.

25 Yes, Dr. Schlenk?



1 **DR. DANIEL SCHLENK:** Just to clarify on
2 the lipophilicity issues relating to atrazine, I was
3 just looking at the log P; it's 2.75. So it actually
4 is fairly lipophilic; it's about 100 times more likely
5 to be in octanol than water, so it's fairly lipophilic.

6 **DR. STEVEN HEERINGA:** Dr. Krishnan?

7 **DR. KANNAN KRISHNAN:** The biological
8 measures of the partition coefficient don't seem to
9 suggest that, from my recollection. But those are
10 within a factor of 1:3, the plasma to various tissues;
11 just an observation, recollection from the data.

12 **DR. STEVEN HEERINGA:** Dr. Horseman.

13 **DR. NELSON HORSEMAN:** I would just say
14 it doesn't much matter. There's a lot of it in the
15 mammary gland. And there's just about every kind of
16 metabolite in the lactating mammary gland, lipophilic
17 and hydrophilic and every other sort of so that
18 doesn't really matter. Whether it's surprising or not,
19 it's there.

20 **DR. STEVEN HEERINGA:** Any other
21 contributions?

22 Dr. Bailar.

23 **DR. JOHN BAILAR:** Just to have it on the
24 record, I would urge EPA to keep its eye firmly fixed
25 on effects of real concern at doses of real concern.



1 Much of the new information we've received for this
2 meeting falls outside one or both of those limits. I'm
3 not saying it's irrelevant; but every time EPA uses
4 data that are either not focused on effects of real
5 concern at doses of real concern, they should say why
6 it is considered relevant.

7 **DR. STEVEN HEERINGA:** Thank you, Dr.
8 Bailar.

9 Just again reminding ourselves,
10 consideration of uncertainties in estimating drinking
11 water exposures and any remaining uncertainties in
12 atrazine's toxicological profile across life stages,
13 particularly assessed in infants and children. Any
14 additional comments or input on life stage?

15 We heard some things, and I think the
16 metabolism suggestion was one and there have been
17 others. So, Dr. Pope and Dr. Chambers and Dr. Fenner-
18 Crisp, other comments people would like to make on this
19 particular question?

20 I'm going to turn to the EPA, and I'll
21 turn to Dr. Fowle or Dr. Lowit?

22 **DR. ANNA LOWIT:** I think the only thing
23 I would ask is implicit in the rest of the text that's
24 not on the screen is that a lot of the water
25 uncertainties were covered in Question 4, basically.



1 If there were anything that weren't covered in Question
2 4 that are relevant here, to make sure they get put on
3 the record.

4 **DR. STEVEN HEERINGA:** Right, okay. And
5 I think again if anyone has anything to add before we
6 close these proceedings, any thoughts that come to
7 mind, you'll certainly have a chance to bring them in.
8 And in the preparation of the report, as you well know,
9 there is reorganization of some of the discussion to
10 make it match the organization of the Charge Questions.
11 Okay.

12 Yes, Dr. Horseman?

13 **DR. NELSON HORSEMAN:** Again, not to drag
14 this out a little bit, but we heard an argument here
15 for monitoring finished drinking water, and clearly the
16 epidemiologists would much prefer that they have that
17 information to understand real exposure.

18 I wonder if given that in general
19 primary and secondary conventional water treatment
20 isn't designed in any sense to remove these components,
21 the extent to which things like atrazine and soluble
22 components are removed in conventional water treatment
23 seems to me sort of accidental and that only tertiary
24 treatment is designed to remove these things.

25 I wonder if aside from the utility of



1 the finished-water information for epidemiology, if
2 this is actually the appropriate charge in terms of
3 knowing finished water and so on.

4 **DR. STEVEN HEERINGA:** Dr. Chambers?

5 **DR. JANICE CHAMBERS:** The reason I
6 suggested that and perhaps the reason Carey suggested
7 that is that the epidemiology exposure information is
8 so weak in terms of, you know, proximity to a cornfield
9 or something like that. If you're going to get a more
10 accurate assessment of what people are being exposed
11 to, you need to look at the actual drinking water.

12 **DR. STEVEN HEERINGA:** Dr. Pope?

13 **DR. CAREY POPE:** Yes, I agree also with
14 what Jan just said; but I believe someone in the last
15 couple of days also showed some differences in the
16 different treatment facilities as far as the incoming
17 and the outcoming, the contents were that I thought,
18 depending on which community water service was there,
19 there were different clarifications of the chemicals.

20 **DR. STEVEN HEERINGA:** I think Dr.
21 Thurman presented a comparative chart, and then I think
22 also Syngenta chart or Dr. Hall, Mr. Hall, Dr. Hall
23 had a chart comparing efficacy of it on about 60
24 different sites as to the removal.

25 And clearly the activated-carbon

1 filtration was the one that appeared to be at least
2 producing null results, and as he went up the ladder
3 where there was no carbon treatment, there was more
4 likely an occurrence of atrazine.

5 Yes, Dr. McManaman?

6 **DR. JAMES McMANAMAN:** One last thing and
7 very brief. I think there could be a wealth of
8 information obtained by examining in laboratory animal
9 studies the fecal content of atrazine. I asked this
10 question the other day to Syngenta and they didn't have
11 the information regarding the amount of atrazine in the
12 fecal content; but they showed studies in which
13 atrazine, dietary dosing of atrazine, had no effect.

14 Well, the only way that we can
15 understand what those studies mean is if we understand
16 how much is actually coming in, and a very simple
17 procedure that could be used is by just examining the
18 amount that was given, the amount that was absorbed,
19 because it's just a simple subtraction.

20 **DR. STEVEN HEERINGA:** Okay. Dr.
21 McManaman, do you feel, I thought we heard there was at
22 least a rough estimate of the percent of excretion in
23 fecal matter. Was this a different --

24 **DR. JAMES McMANAMAN:** That was from a
25 gavage dose, not from a dietary dose.



1 **DR. STEVEN HEERINGA:** Thank you. Thank
2 you, thank you.

3 Dr. Horseman, you have something
4 additional?

5 **DR. NELSON HORSEMAN:** No.

6 **DR. STEVEN HEERINGA:** Any additional
7 comments on this?

8 Okay. Again, we'll return and give
9 everybody a chance for some final wrap-up comments.

10 Let's move on, then. I can see we're
11 going to easily make 12:00 o'clock unless this breaks
12 down.

13 But good, good. I think it's been
14 productive, all of these discussions.

15 So Question 6, I'm going to rotate here.
16 Mr. Fowle or Anna?

17 **DR. ANNA LOWIT:** Question 6: Please
18 comment on the Agency's analysis and preliminary
19 conclusions contained in Section 8.0 in the draft Issue
20 Paper as it relates to the potential critical windows
21 of exposure. Please include in your comments
22 additional or alternative approaches or data that may
23 inform this issue.

24 **DR. STEVEN HEERINGA:** For our
25 integrative analysis, we'll turn to Dr. Bucher to



1 start.

2 **DR. JOHN BUCHER:** Thank you.

3 So in preparation for this, I sent some
4 preliminary remarks around to the group earlier on, and
5 I got a reality check back from Dr. Coupe on some of
6 the comments I had made with respect to water systems;
7 so I acknowledge his contributions here, and also Dr.
8 Meek sent me some comments to integrate into this
9 document as well.

10 So Section 8 in the Atrazine Issue Paper
11 systematically addresses a number of issues. These
12 include: the use of the LH surge suppression in the
13 rat as a benchmark response; the strength of evidence
14 linking the benchmark response with a variety of
15 endpoints in human epidemiology and experimental animal
16 studies; the comparative timing and extent of exposures
17 with respect to the potential to suppress the LH surge
18 in animals and humans, including kinetic and dynamic
19 considerations; the potential for water atrazine
20 concentrations exceeding a level of concern to be
21 missed by current sampling procedures; and the concept
22 that sampling frequency can be meaningfully adjusted
23 based upon the potential for human health outcomes.

24 The Agency has done a good job of
25 summarizing the situation in each of these areas with



1 respect to the uncertainties and limitations in both
2 the data and in our scientific understanding of what
3 these data are telling us.

4 The Agency has determined that the
5 collected information suggests a water-sampling
6 frequency of between a few days and four weeks based on
7 durations of exposure considered relevant with respect
8 to potential human health outcomes. Currently, the
9 sampling frequency required to the registrant is once a
10 week during the use season and once every two weeks
11 during the rest of the year.

12 There are a whole series of assumptions
13 and extrapolations that contribute to this proposed
14 critical window of human exposure, and given the
15 collected uncertainties that these assumptions
16 introduce, the imprecision in this proposed sampling
17 frequency seems fully justified.

18 This may be about as precise an estimate
19 as can be obtained when starting with the experimental
20 animal data and the exposure requirements for the LH
21 surge suppression, as opposed to using outcomes that
22 are more unequivocally adverse.

23 In this regard, the consideration of
24 human relevance of the adversity of the LH surge
25 suppression on the basis of both the pharmacokinetics



1 and the pharmacodynamics, taking into account the
2 broader database, including data on other
3 pharmaceutical agents that have been used to block the
4 LH surge, is to be commended.

5 After all this, the proposed range of
6 human exposures responsible for potential adverse
7 outcomes still appears to be little more than an
8 educated guess.

9 Question 6 specifically requests
10 alternative approaches and, in fact, there is another
11 way of approaching this that may be useful, at least
12 when setting the boundaries of exposures that may
13 present a concern for human health effects.

14 The current epidemiology database is
15 characterized as providing suggestive evidence that the
16 mechanisms of action thought to be operative in rats
17 may be occurring in humans exposed to atrazine. The
18 Agency has appropriately concluded that the limited
19 human evidence is insufficient to establish causality
20 and does not provide sufficient quantitative exposure
21 information to use in a risk assessment.

22 However, what if one assumes that the
23 reported human health outcomes are, in fact, due to
24 current levels of exposure to atrazine? Although the
25 water-sampling data may not be adequate to assure that



1 atrazine peaks are captured in all water systems,
2 clearly, some of the patterns we have seen are based on
3 rather comprehensive datasets.

4 These patterns of atrazine
5 concentrations in water could provide reasonable
6 estimations of the extent and duration of human
7 consumption of atrazine following agricultural
8 applications for re-emergent weed control.

9 I would suggest that this represents an
10 alternative approach to getting at levels of atrazine
11 in drinking water that may represent risks to human
12 health.

13 These risks could be compared certainly
14 on an order-of-magnitude scale against those calculated
15 from the animal data and may provide a lower bound
16 conservative floor from which to work and provide a
17 different perspective on the water-sampling frequency
18 problem.

19 This would put the Agency in a much
20 better position if, in fact, the agricultural health
21 study or the other epidemiology studies that are
22 ongoing or may be done in the future provide further
23 support for human health effects as the results
24 continue to accumulate and be reported.

25 The other consideration when faced with



1 an uncertainty over a critical exposure window of a few
2 days to four weeks is whether basing sampling frequency
3 on human health effects is, in fact, the best course of
4 action.

5 Atrazine concentrations in a stream and
6 subsequently in the finished water supply or the
7 community water supply that uses that steam as its
8 water source are dependent upon many factors that vary
9 spatially and temporally.

10 As was discussed yesterday, each
11 community water system is unique in factors that affect
12 the delivery of atrazine, such as a drainage base and
13 size, characteristics of the soils, cropping patterns,
14 slope, et cetera, as well as whether the community
15 water source and water intake is directly in the steam,
16 in a reservoir or in an off-stream storage facility.

17 In addition, there are many factors that
18 affect the ability of a water-treatment system to
19 remove atrazine from water such as use of activated
20 carbon and the type of oxidant. It's also been shown
21 that the amount of atrazine in the system can sometimes
22 be related to the ongoing maintenance of the treatment
23 plant.

24 So, in fact, it may be more useful to
25 consider a strategy that I believe was reflected in



1 yesterday's discussion of Questions 3 and 4, which was
2 to capture the pattern of atrazine in the source water
3 for each community water system based on the
4 characteristics of that particular water system, as
5 opposed to this one-size-fits-all approach that has
6 been put forth based on the series of health-based
7 considerations by the Agency.

8 Given the collective limitations of the
9 health outcome-based approach, this would seem prudent
10 and would again put the Agency in a better position to
11 take further action, should the results of ongoing
12 epidemiology studies provide more convincing evidence
13 of human health effects.

14 Thank you.

15 **DR. STEVEN HEERINGA:** Thank you, Dr.
16 Bucher.

17 Dr. Coupe?

18 **DR. RICHARD COUPE:** Good morning. I
19 don't really have much to say. I just have kind of
20 like a, not even an opinion, really, just kind of a
21 feeling. I appreciate Dr. Bucher putting all that
22 together; that was really nicely done.

23 My feeling is that I'm really kind of
24 somewhat conflicted as I sit here, as after we sit here
25 for a couple of days and we've tried to and not being



1 a toxicologist, some of it was rather mind-numbing,
2 trying to figure out, you know, does atrazine affect
3 human health in any way, shape or form at levels that
4 are environmentally significant, and it was very
5 difficult for me to see that there was such a thing.
6 Coming from an agricultural background, I know how
7 important atrazine is and I was dying to ask the
8 agricultural people some questions; but then you said,
9 you know, keep it relative to the Charge Questions.
10 But nothing they said was relevant to the Charge
11 Question.

12 But I understand where they're coming
13 from. You know, atrazine is very important to modern
14 agriculture; it's also important in urban areas. I
15 mean, we all probably use atrazine. If you use weed and
16 feed, it's got usually atrazine, may be 24d or
17 something else in it, we all use it. It seems a little
18 unfair based on what we see as the health effect right
19 now to ask the registrant to do more than they are
20 currently doing.

21 You know, we have had this debate about
22 finished water and surface water. I mean, I understand
23 the debate, and I think, you know, let's do both. That
24 seems a lot to ask. I don't want to lose the surface
25 water, because when you go to the finished water,



1 although it's good for the epidemiologists, you lose
2 kind of the tie to the environmental system.

3 And so it makes it much more difficult
4 to predict what the environmental effects, the slopes
5 and cropping and all that, had to do with how atrazine
6 gets delivered to the intake. So I would hate to see
7 us lose that, but I understand why we'd want to go with
8 finished water.

9 And then that all being said, on the
10 other hand, atrazine is used so much that it is
11 currently found in every environmental compartment that
12 we've looked at: it is in the rainfall, it is in the
13 drinking water, it is in the surface water, it's in
14 reservoirs, it's in lakes, it's in lakes and reservoirs
15 far from any point of application; it's carried by the
16 atmosphere.

17 And so it seems like we ought to, since
18 it is such a widely used one, we do need to kind of be
19 careful with it, 'cause what if it is having some
20 subtle effect? What if what Dr. Bucher said is that
21 we're already seeing the effect; it's just so broad,
22 you know, we can't see it anymore, but it's there. I
23 know that's a bit confusing; but that's just kind of
24 like where I'm conflicted at at this point.

25 I think that's all I want to say.



1 **DR. STEVEN HEERINGA:** Thank you, Dr.
2 Coupe. Appreciate those thoughts.

3 Dr. Fenner-Crisp?

4 **DR. PENELOPE FENNER-CRISP:** I should
5 note that even being a toxicologist, it was mind-
6 numbing.

7 There was a whole lot of data there;
8 talk about supersaturation.

9 Obviously, I'm on board with what John
10 has written, because we've had a chance to work on it.
11 I wanted to add a technical comment from something
12 that's in the chapter.

13 You've offered an example here of what
14 would the numbers look like if you used that allometric
15 scaling? It was Table 8-1 on Page 128. The thing that
16 drew my attention was it was being based on a human
17 female of 60 kilograms.

18 The average human body weight for women
19 in the U.S. hasn't been that low for over 50 years. So
20 I found a National Health and NCHS report that was
21 published in 2008 that captured anthropometric
22 reference data for children and adults for the years
23 between 2003 and 2006.

24 I'll provide the citation. I don't
25 think they published the update for 2006 to 9. But in



1 this, the average body weight for the U.S. female is
2 165 pounds. So if one chooses to go forward with
3 allometric scaling in testing the possibilities in the
4 quantitative component, I would suggest you update them
5 to some reality. I found that rather startling, quite
6 frankly.

7 **DR. STEVEN HEERINGA:** Thank you, Dr.
8 Fenner-Crisp.

9 Dr. Greenwood?

10 **DR. RICHARD GREENWOOD:** Well, I, excuse
11 me, very much agree with the tone of what Dr. Bucher
12 presented, and I agree with the Agency that there's a
13 lot of scientific uncertainty in estimating these
14 critical levels of exposure in terms of critical doses,
15 concern sort of corresponding to any critical plasma
16 concentration and a critical time period of exposure as
17 sort of a duration of critical plasma concentration.

18 And they're trying to sort this out in
19 the absence of knowledge of any primary lesion or of
20 the minimum disruption that will lead to various
21 secondary lesions that we heard a lot about during this
22 week.

23 And so I understand also that they've
24 got difficulty in trying to assess human plasma areas
25 under the plasma-concentration curve in humans that



1 would correspond to particular intakes of drinking
2 water, and I will sort of come back to that at the end.

3 I found it difficult to assess the
4 relevance of the information on the GnRH antagonist
5 research, because the Mode of Action is quite
6 different.

7 Really, we have no data to provide any
8 guidance at all about what would be the minimum
9 concentration of atrazine that would be needed over a
10 period of exposure that would produce an equivalent
11 reduction in GnRH level to match the antagonism of the
12 receptor that we see with this drug.

13 It's very difficult to tie any of the
14 atrazine data into that, and it's difficult to see how
15 you would use that to identify an exposure to atrazine
16 that would produce a similar effect at that critical
17 period that was identified.

18 I think the data presented by the Agency
19 and by Syngenta demonstrate that repeated dosing, which
20 is the sort of case we'd have with human exposure via
21 drinking water, would lead to some sort of pseudo-
22 steady state if the dose was constant.

23 And the Syngenta data indicate that the
24 plasma profile is very much smoother when atrazine is
25 presented in food rather than in a discrete bolus by



1 oral gavage. But administration in drinking water I
2 think would probably fall somewhere between these two
3 scenarios, and it would be depend of course on the time
4 and nature of meals relative to drinking the water.

5 So although the area under the plasma
6 curve sort of represents internal exposure resulting
7 from dose in it, we need to be a little careful.

8 It is important, I think, because this
9 will provide a link between external exposure and site
10 of action, and it could be important if the dose varied
11 from day to day as it may well do in human exposure,
12 because under the regimen of regular dosing over a
13 fixed time with a constant dose, it's just the
14 calculation of the area and the curve is redundant, and
15 the plasma concentration is the only variable needed.

16 And I think it would be helpful for the
17 Agency to have some idea of whether area under the
18 curve really is important, and it's difficult to see
19 that or to conclude that on the basis of the existing
20 data.

21 If we look at the papers of Kamel and
22 Stoker that were provided in the docket, look at the
23 evidence they provided, then I think it's wholly
24 appropriate to use the area under the curve as a
25 measure of exposure, because that does give an idea of



1 the opportunity of exposure of individual tissues.

2 And the work that is being done at the
3 minute to get good estimates of plasma-tissue partition
4 coefficients may overcome some of the problems
5 highlighted by the Agency in the discussion in Section
6 8 of the white paper, because it will give further
7 insight into exposures of individual tissues.

8 I think the whole business has been
9 slighted by the fact that the DACT binds to a range of
10 proteins in each tissue that's being looked at, and
11 this could be a complicating factor, depending on the
12 amount of covalent binding in particular tissues,
13 because then eventually for elimination of the bound
14 material, it will depend on the time scale of turnover
15 of proteins, and of course that can range from hours
16 for enzymes involved in metabolic regulation to weeks
17 for structural proteins; so it would depend on the
18 pattern and extent of binding.

19 Now, this sort of binding would only
20 become important if it was that that produced the
21 primary lesion. I'm not sure whether we're anywhere
22 near understanding that at all; I don't think we are.

23 But I do think I agree with the Agency
24 that the physiologically based pharmacokinetic modeling
25 approach is the ideal route if they want to take all of



1 these uncertainties in account and extrapolate from
2 rodent to human.

3 But I think in the absence of that at
4 the moment, the Agency is taking the best approach
5 that's available to it, and that is to use the
6 pharmacokinetic approach that they have used.

7 But it is I think one question that
8 really should be approached, and that is to try and
9 determine whether there really is a critical area under
10 the curve -- that is, a critical exposure of a target
11 site -- that leads to a given level of suppression of
12 the LH surge, because I think at the moment if you give
13 a constant dose over the four days, it doesn't tell you
14 very much at all.

15 What you really need to do is to get the
16 same area under the curve by different dose regimens,
17 because there is a number of possibilities in there.
18 One is that they're not equally susceptible or equally
19 tolerant, if you like, on all days.

20 It could be, you know, you need 100
21 units exposure on 1 day, but only 50 on the next. Are
22 they equally susceptible over the whole of this
23 critical period that's being used? Do you need all
24 four days, or is it sufficient to do Days 2 and 3?

25 So there could be a critical exposure



1 time combined with a critical level, and it would have
2 the same nexus area under the curve; but there would be
3 a minimum to it. There would be a minimum exposure
4 time and that would be fixed, and then you may find
5 that there is a minimum concentration that you need to
6 maintain over that period.

7 But at the minute, I don't think any
8 experiments are being done, really, to determine
9 whether it's area under the curve or whether it's just
10 a critical concentration for a critical time, and the
11 two are different, because if you could give, for
12 instance, a low dose on Day 1, a very high dose on Day
13 2, a low dose on Days 2 and 3, or you could give a
14 moderate dose over the four days or any combination
15 that will give the same area under the curve, but do we
16 know whether that would actually give the same
17 biological response? And I think the answer at the
18 minute is no; it's just giving the design of the
19 experiments that are being done.

20 So I think this could be important; it
21 could have important implications for humans besides
22 just another area of uncertainty, unfortunately.

23 But given the variability in the water
24 sources and both temporally and spatially and all of
25 the added variability because you got different



1 efficiencies of water treatment plants, and even
2 identical water treatment plants could work with
3 different efficiencies --

4 I think that's something that's been
5 observed throughout the world -- it's difficult to see
6 at the minute how more refined monitoring would really
7 help to predict or catch peaks in all the individual
8 community water treatment plants in a sort of cost-
9 effective way.

10 And I think one of the things the Agency
11 might consider - and this again is something that Dr.
12 Bucher has raised -- is to actually look at what are
13 the likely exposures in humans, given the information
14 we know about the variability in water treatment plants
15 and in the drinking water.

16 And it might be worth just using some
17 simple model to try and estimate internal exposures
18 corresponding to some of the patterns of fluctuation in
19 water concentrations that you see. So if it's a very
20 quick peak going over a day or two days, given the
21 amount of water that a human would drink, what's the
22 implication if that's then followed by three low days?
23 Just going to some of the chemographs that are
24 available, because we've got a lot of good data to play
25 with, it then might be worthwhile to say: what would



1 happen if then we used an average concentration over
2 the period? What would be the difference in terms of
3 the total exposure that you'd calculate?

4 So at the moment I think, you know,
5 people have been concentrating on the drinking-water
6 variability but maybe not looking at the impact this
7 might have, and then trying to relate that back to some
8 of the other potential endpoints that Dr. Bucher
9 identified.

10 I know that it's very difficult to try
11 and extrapolate from rodents to humans in terms of
12 bioavailability. It's very easy to extrapolate from
13 rodents to humans in terms of absorption from the gut,
14 because they're highly correlated.

15 But the bioavailability is quite
16 different for many pharmaceuticals, for instance,
17 between rat and humans. So that would need to be
18 considered when you do any modeling. But I think Kow
19 and coworkers in 2006 actually gave quite a nice
20 discussion of, you know, how you might move between or,
21 rather, some of the difficulties in moving from rodents
22 to humans.

23 So I've tried not to repeat what's gone
24 before; but I think it's pulling some of the stuff that
25 other people have raised earlier together, and I think



1 I'll leave it there.

2 **DR. STEVEN HEERINGA:** Thank you very
3 much, Dr. Greenwood.

4 Dr. Bucher, did Bette leave you any
5 comments on this, or you already incorporated those?

6 **DR. JOHN BUCHER:** Bette left me a few
7 comments that I did incorporate into the statement that
8 I gave.

9 **DR. STEVEN HEERINGA:** Thank you.

10 Dr. Mumtaz?

11 **DR. MOIZ MUMTAZ:** Yeah. The use of any
12 chemical in the environment I believe has consequences
13 good and bad, and John has captured the Panel's views;
14 but I also was thinking about Dr. Coupe's comments.
15 And it is we go to community meetings, and we get that
16 hearing is most of the time is what we hear from the
17 public and the community.

18 So we should neither compromise public
19 health or ecological health, but not impose undue
20 restrictions on the producers of chemicals. And so we
21 try to be as realistic as possible in what we do.

22 In the report and throughout the last
23 three or four days, we have discussed only two issues;
24 one is the LH surge, and I think I've learned enough
25 about it hopefully, I can retain some of it to use in



1 the future work -- and the other one is the mixture of
2 atrazine and its three metabolites.

3 So as opportunity approaches, one of the
4 things I would like to suggest is to look at methods
5 that can be used to get an idea about the potency of
6 these various chemicals, just the metabolites -- and I
7 said this yesterday about use of computational tools --
8 to build the weight of evidence to have some idea about
9 what these metabolites' potency is and what their
10 relative concentrations would be, and we discussed this
11 in the pharmacokinetic section.

12 Earlier, we talked about children's and
13 infants' health, and that's something also we have to
14 keep in mind in terms of the sensitive populations,
15 their enzyme levels and the quality of the enzyme
16 changes, and so we have to keep that in mind when we
17 think about the toxicity of chemicals in general.

18 And so I want to move away from the LH
19 and look at other toxicities. I think EPA should look
20 into neurotoxicity, hepatotoxicity by the way, there is
21 a toxicologic profile on atrazine and it's a dated
22 document; but it still has a lot of useful information.
23 And there's a lot of data in animals on other
24 toxicities, and that's something we should look at as
25 an Agency.



1 And so when we do that, if we look at
2 greatest toxicities and we are looking at using LH as
3 the driver, it would help us make the case for the
4 decision we are making rather than look at one and hang
5 everything on that one tree or branch or basket or
6 whatever the case may be.

7 So I would like EPA to look at other
8 toxicities and show that this is within a range so that
9 when we make a decision, it will be useful.

10 And so we all talked about PPK model
11 that is ideal. And Karen is sitting next to me, I
12 think, and Janice and Mel, they all have done wonderful
13 job in promoting the PPK modeling concepts.

14 But ultimately it will give us an
15 internal dose, either in a particular tissue of
16 interest or a particular organ; but we still have to
17 determine what is that organ which we're interested in,
18 and so we have to look at what I call legitimate
19 mixtures.

20 So it is great, you know, to have done
21 this research on the limited mixture, but is that a
22 legitimate mixture? Is that the actual exposure that
23 is occurring in the environment, to the public and
24 across the country?

25 As I mentioned, apart from herbicide



1 triazines, we use organophosphates in farms. There's a
2 lot of other chemicals, the farm chemicals that are
3 being used. And it will be a good idea to look at the
4 U.S. Geological Survey data and see what other
5 possibilities exist and look into the overall joint
6 toxicity of those chemicals in keeping part of this,
7 again making a realistic decision.

8 So having said all that, I don't want
9 this to come as a criticism of EPA; I think they have
10 done a wonderful job and we all, in their world, the
11 issues are quite challenging. And we are making
12 progress and as long we're making progress, I think we
13 are in good shape, and I thank you for the opportunity.

14 **DR. STEVEN HEERINGA:** Thank you, Dr.
15 Mumtaz.

16 Dr. Chambers?

17 **DR. JANICE CHAMBERS:** Dr. Mumtaz, you
18 were not at the last atrazine meeting; so you didn't
19 know that we spent several days talking about other
20 types of toxicity. We looked at neuro and immuno and
21 some of the other things, and the conclusion of the
22 Agency and the Panel was that the LH surge data was
23 really the most sensitive and most reliable database
24 for consideration.

25 **DR. MOIZ MUMTAZ:** But, Dr. Chambers, the



1 problem is whether this is the primary target, and how
2 do you, you know, the extrapolation from LH surge to
3 actual toxicity in rats has been somewhat established;
4 but whether that same mechanism works in humans is
5 something which we are debating.

6 So I'm not saying that this is the wrong
7 thing; I'm just telling that we should develop a maybe
8 we should put that information as a summary in this
9 report so that people like me can say, "Okay, EPA has
10 done this wonderful job" and I can retract that
11 information.

12 So it will be nice whenever you're
13 presenting something to say, "We looked at all these
14 things, and here's what we think: this is all within
15 this certain range or order of magnitude" or whatever
16 so that we can put the overall profile of the chemical
17 or its mixtures in perspective.

18 **DR. STEVEN HEERINGA:** I think there were
19 some good suggestions along those lines yesterday in
20 the discussion of the mammary gland.

21 Dr. Horseman?

22 **DR. NELSON HORSEMAN:** I just wanted to
23 say that there seems to be a sense of things maybe
24 having it both ways, so to speak.

25 So with regard to the notion of



1 neurotoxicity, we understand maybe that the previous
2 SAPs have looked at neurotoxicity per se; but at the
3 same time, a neural neuroendocrine mechanism is being
4 proposed as the underlying phenomenon that drives this
5 change in LH surge.

6 So clearly you can't say that you have
7 no neurotoxicity, but the toxicity you're using as the
8 driver for this regulatory decision has a neural
9 mechanism underlying it.

10 So I think Dr. Mumtaz's point -- and Dr.
11 McManaman has made it, and several other people have
12 made it -- that these may be, these effects that we're
13 talking mostly about at this meeting may be epi
14 phenomena of some other mechanisms that may not
15 manifest in primary toxicity in the neural system but
16 may drive metabolic and neuroendocrine changes. So I
17 just want to make that distinction.

18 **DR. STEVEN HEERINGA:** Dr. Legan?

19 **DR. SANDRA LEGAN:** So in view of the
20 discussions so far this morning, there's a lot of
21 problems with trying to get data about an adverse
22 effect of this pesticide in a rodent population and
23 compare this or extend this somehow to human doses and
24 effects and so forth.

25 And this is going to sound, this is a



1 little outside the box, but something that I think
2 ought to be just thought about and raised, so I'm
3 raising the issue is that out in the fields and out in
4 the environment where the atrazine is being, you know,
5 put on the fields, there's a lot of rodents.

6 There's field mice involved, et cetera,
7 as we all know, and we're focusing on rodents here.
8 Obviously, there are amphibians and worms, et cetera.

9 But having said that, there is no field
10 biologist here on the Panel, and field biologists
11 routinely fit birds, et cetera, including rodents, with
12 radio frequency chips. I mean, they do it with whales
13 and everything. So we know they can do this, and they
14 can track, you know, where these animals roam.

15 And they already know what the range of
16 where they live, you know, what the range is in their
17 territories. Like for a mouse, it's X -- it's probably
18 less than an acre, but who knows?

19 Okay, but they know. And it seems to me
20 you could sample some of these animals. You could also
21 establish what their range is in relation to where the
22 atrazine, what fields. And apparently, I mean, how in
23 Illinois or Indiana there's thousands of acres. These
24 animals don't probably go much outside of that area
25 where the atrazine is being used.



1 So you could do survival curves on
2 animals. You could just watch until the radio
3 frequency thing stops moving. You know, I mean, for a
4 large length of time, there's got to be a way to do
5 this. You could just do survival curves to see if
6 they're surviving or not.

7 And if you trap, you can live-trap them
8 and then you have a population. If you get high
9 numbers, you can look at their reproductive systems,
10 their brains, et cetera. You can take every piece of
11 tissue and analyze it for atrazine and all its
12 metabolites.

13 I assume. We do that in lab rats, so we
14 just should this is, like I said, is outside the realm
15 of what we've been discussing to some extent; but it's
16 totally relevant if field biologists could do these
17 things and it could be used in areas where we know
18 there's the highest concentrations of atrazine have
19 been used over the last X, 50 fifty years was it in
20 some places we heard from some of the people?

21 So it's a thought, it's not a complete
22 thought; but it's right there out in nature, data. And
23 we wouldn't maybe know their exposure, but still there
24 would be a lot of information that we could glean from
25 that.



1 I think that might be useful in just
2 trying to extend from rodents to humans out where the
3 pesticide is in levels where the organisms are living,
4 whatever the shape of the chemograph, et cetera, et
5 cetera.

6 **DR. STEVEN HEERINGA:** Thank you, Dr.
7 Legan. There is just a comment here. You know, there
8 is a substantial amount of work on pesticides and
9 herbicides and non-human health effects, environmental.
10 And for those of us who have been here for ages, it
11 seems there have been focused not only on terrestrial
12 but also amphibian and aquatic; and I think, if I
13 recall correctly, a lot of the emphasis on non-human or
14 environmental effects has shifted to aquatic.

15 There has been some work in terrestrial;
16 but, again, there's quite a body of work that's ongoing
17 of that nature, including discussion of field biology
18 and how that can play into informing exposures that are
19 non-human.

20 Dr. Mumtaz - or, Dr. Krishnan and then
21 Dr. Mumtaz.

22 **DR. KANNAN KRISHNAN:** I just, if you're
23 done with the designated discussants, I thought I would
24 add some comments.

25 I concur with Dr. Bucher's and Dr.



1 Greenwood's analysis and comments. I just want to add
2 a couple. The first one relates to the use of the
3 allometric scaling of the rodent pharmacokinetic data
4 in relating to the duration of human exposure. Some of
5 the results were presented in Table 8-1 and associated
6 discussions.

7 I mean, I agree with those calculations
8 to inform about the duration, the way it was done;
9 however, but the use of such a calculation to derive a
10 human equivalent dose here would not seem appropriate,
11 because there are two things here when you do the
12 allometric scaling or use of the elimination half-life.
13 One is to inform about the possible duration to get to
14 a steady state, if you will.

15 That seems appropriate to me, whereas
16 using the allometric scaling to calculate the human
17 equivalent dose is questionable. I'm not convinced
18 that it's correct, because when we do the allometric
19 scaling or when we apply the body surface scaling to
20 calculate the human equivalent dose from the animal
21 dose, it's to have the same parent chemical
22 concentration in both systems.

23 So we are adjusting for the clearance so
24 that there is equal parent chemical concentration.
25 Here it's a bit tricky, because we know that it's not



1 just the parent chemical concentration at steady state
2 that's of concern; it's actually the rest of it as
3 well. So it's kind of a mix of both: the clearance of
4 the parent chemical, as well as the clearance of the
5 metabolites.

6 So you have to consider both of them
7 together. The KEL that you do separately to inform
8 about the duration, and then the body surface scaling
9 that you do separately, those have to be really
10 combined to drive it. There is some literature on it;
11 why, we can put it in the report in terms of reference.

12 Then the other comment I want to make in
13 terms of the duration considering the Mode of Action
14 and toxicity profile on water monitoring is that I am
15 thinking about based on the datasets, I mean, tox
16 datasets, it's actually from a few days to four weeks
17 which is fine, because the 28 days or a month, you
18 know, reflects the human exposure during the cycle as
19 the few days as the rat, four or maybe one or two days,
20 questions are being raised.

21 I'm more thinking of one cycle in the
22 rat versus one cycle in the human. But in
23 consideration of that, I think the combined use of the
24 steady-state consideration for pharmacokinetics as well
25 as the similar average attenuation effect across



1 durations, those two key pieces put together in my mind
2 really make a case as to whether it's really needed to
3 decrease the duration of the monitoring frequency. I
4 mean, that really makes, that really tells me; that's
5 more like a textbook example.

6 It's actually a nice case study, the way
7 the steady-state concentration is being used along with
8 the similar LH across duration; so the way it's
9 presented in Chapter 5 and the way it's brought back
10 into 8. So based on that information, I don't see a
11 compelling argument for less than a weekly monitoring.
12 That's just my thought.

13 **DR. STEVEN HEERINGA:** Thank you, Dr.
14 Krishnan.

15 Dr. Mumtaz, you had something?

16 **DR. MOIZ MUMTAZ:** I just wanted to
17 follow up on Dr. Legan's comment that once upon a time
18 when we started talking about hazardous waste sites and
19 looking at health effects, there were a lot of studies
20 done to look at the enzyme levels in wild animals,
21 particularly rats and mice, on the hazardous waste
22 sites, and some of the sites are hundreds of acres;
23 they are not a small site. And I know not far from
24 here, the protected Wildlife Refuge in Maryland, Dr.
25 Ratner, does that kind of work, so there is some



1 database there we could look into.

2 **DR. STEVEN HEERINGA:** Okay. At this
3 point, I think it looks like we've sort of reached the
4 coverage on Question No. 6. I'll turn to Dr. Lowit,
5 Nelson Thurman, any okay.

6 At this point in time, what I would like
7 to do is to just go around the Panel once, and I'll
8 start with Wes Stone to see whether there are any
9 additional comments that you'd like to make related to
10 these proceedings to put on the record or

11 **MR. WESLEY STONE:** Thank you, no, I'm
12 fine.

13 **DR. STEVEN HEERINGA:** Dr. Coupe?

14 **DR. RICHARD COUPE:** Fine also, thank
15 you.

16 **DR. STEVEN HEERINGA:** Dr. Lee.

17 **DR. HERBERT LEE:** I guess one extra
18 comment I just sort of thought of was that mostly we've
19 been thinking, looking at the question of are we
20 monitoring frequently enough, looking at the water
21 sources, and depending on duration of interest that may
22 or may not be often enough; but on the flip side,
23 outside of the growing season, are we monitoring more
24 often than we need to, is another question possibly to
25 think about. If we're not really ever finding high



1 atrazine concentrations outside the growing season, we
2 may not need to have samples every two weeks. I don't
3 think we really thought about it at all. Maybe that is
4 worth thinking about a little bit.

5 **DR. STEVEN HEERINGA:** Thank you, Dr.
6 Lee.

7 Dr. Akana?

8 **DR. SUSAN AKANA:** Is this on Question 6
9 or the entire meeting?

10 **DR. STEVEN HEERINGA:** The entire week.

11 **DR. SUSAN AKANA:** Oh, okay.

12 **DR. STEVEN HEERINGA:** Including Question
13 6.

14 **DR. SUSAN AKANA:** I woke up in the
15 middle of last night thinking about Dr. Honda's data.

16 Honest. I did, I did. And I, I've
17 been, my own personal nugget is in the HPA system; I'm
18 still struggling with how atrazine interacts with the
19 HPA system, and I was thinking again specifically of
20 his figure of c-fos in the PVN.

21 And I woke up thinking about this, and I
22 was slightly disturbed because in my own mind the
23 micrograph did not include a landmark that I was
24 looking for. So if you're in PVN and if you're talking
25 about the CRF, I was looking at medial parvocellular.



1 And I didn't see the magnocenter of cells in those
2 micrographs, and it really disturbed me.

3 So then what I keyed, what it keyed me
4 to is on the flight down, I read a new paper, a 2010
5 paper. And it's from the King's College group; it's
6 Kevin O'Byrne and Stafford Lightman's group, and the
7 title of it is "Corticotropin-Releasing Factor Alters
8 the Timing of Puberty in the Female Rat".

9 And I'd like to put this into my notes,
10 because what I know of is that CRF, when you think of
11 stress, you think of the medial parvocellular or PVN.
12 But CRF actually is a distributed system; we find it in
13 many interesting areas, and it's probably an integrated
14 circuit for chronic stress.

15 But CRF, I specifically asked Dr. Honda
16 did he look at areas of the BNST and the amygdala.

17 However, CRF is also found in the MPOA.
18 And in this really interesting paper, they describe
19 what apparently is well-known in the literature, is
20 that the CRF there does have connections to the
21 gonadotropin-releasing hormone neurons; and there are
22 the appropriate receptors, the CRF R1 and R2. And in
23 this paper, if you apply CRF ICV you can delay puberty,
24 and if you give the CRF antagonist you can advance
25 puberty.



1 So I think that this gives an area of
2 connection that we were sort of searching for when
3 we're talking about what are the upstream effects that
4 are modulating the decrease in LH amplitude. So I
5 think there might be more here to work with than I was
6 originally groping for.

7 Thank you.

8 So the paper, I would like to put in my
9 comments.

10 **DR. STEVEN HEERINGA:** Thank you; and
11 we're sorry we disturbed your REM sleep, but I think
12 we've all been there. So not exactly on the
13 toxicology, but
14 Dr. Fenner-Crisp?

15 **DR. PENELOPE FENNER-CRISP:** I can't top
16 that, so I'm through.

17 **DR. STEVEN HEERINGA:** Dr. Gold.

18 **DR. ELLEN GOLD:** I actually did have one
19 comment. I like Dr. Legan's thinking-outside-the-box
20 approach and I wanted to extend it to thinking about
21 human studies outside the box, because I think a lot of
22 the agricultural health studies, for example, rightly
23 focuses on the series of applicators; but they don't
24 include a lot of women, they aren't very diverse, as I
25 mentioned in my comments.



1 And it actually is possible to study
2 farm workers, for example. And there are thousands of
3 farm workers, for example, working in cornfields, for
4 example. And we've actually been able to do studies of
5 menstrual-cycle characteristics and collect urine
6 samples in such women.

7 So I would encourage in the long-term
8 view to think again outside the human-study box that
9 they seem to be in and extend the research beyond it,
10 actually look at real-life populations that may have
11 exposure that can be documented.

12 **DR. STEVEN HEERINGA:** Thank you, Dr.
13 Gold.

14 Dr. Harris?

15 **DR. SHELLY HARRIS:** And I'm going to
16 bring us back to water monitoring. I've been thinking
17 about this for the last few days, and there's an
18 assumption that's being made and I keep hearing around
19 the table that the epidemiologists want measures in
20 finished drinking water.

21 And we've been having a few side
22 conversations about that and I say, "Yes, we would like
23 measures in finished water over top of those in
24 environment"; but I also say, "We would like both,
25 ideally".



1 But realistically what can we do with
2 those measures in finished drinking water, and we could
3 certainly use those to improve the ecologic studies;
4 but we've really agreed that those are not particularly
5 useful for risk assessment. So do we want to spend a
6 lot of time and effort improving the group-level
7 exposure assessment for ecologic studies? And my short
8 answer would be, "No, that wouldn't be a priority for
9 me".

10 So what can we do with these low-level
11 measures of atrazine and metabolites in drinking water
12 supplies, and if we're going to conduct very good
13 studies, well, we would look at those at the community
14 level and then ideally at the top level, and then we
15 would take additional, collect additional data on
16 whether people filter their water or not; how much
17 bottled water they drink; how much time they spend away
18 traveling away from home.

19 So how much community water did we drink
20 this week; the consumption in canned products such as
21 tomatoes, another major source of water consumption in
22 humans; and the list goes on.

23 So when we design those kinds of
24 exposure-assessment studies to exposure to water or
25 your source of water, these things all become very



1 important. So what's at the community level that's
2 measured from the treatment facility may have very,
3 very little relation at all to what the human is
4 actually exposed to.

5 And I might suggest a correlation of,
6 you know, 20 percent, if we're lucky, it might 70
7 percent. I'm not sure. We could look at enhanced data
8 and those types of data in relation to some of these
9 finished and unfinished measures and get a feel for
10 that. And we could also conduct some really decent
11 biomonitoring studies. And I think that some of that
12 should be done.

13 But I think before really significant
14 resources go into looking at finished-water supplies
15 where you've got, I'm assuming, a lot of non-tapped
16 that we should look at whether they're going to be
17 relevant for estimating low-level human exposures. We
18 have very little ideas of how frequently we need to do
19 that, the windows of susceptibility and that kind of
20 thing.

21 So that's sort of my wrap-up on my
22 thoughts about that, thanks.

23 **DR. STEVEN HEERINGA:** Thank you, Dr.
24 Harris.

25 Dr. Bailar.



1 DR. JOHN BAILAR: Nothing to add.

2 DR. STEVEN HEERINGA: Dr. LeBlanc?

3 DR. GERALD LEBLANC: Nothing.

4 DR. STEVEN HEERINGA: We'll go to Dr.

5 Legan?

6 DR. SANDRA LEGAN: No further comments.

7 DR. STEVEN HEERINGA: Okay. Dr.

8 Delclos?

9 DR. BARRY DELCLOS: I'm fine.

10 DR. STEVEN HEERINGA: Dr. Roby?

11 DR. KATHERINE ROBY: I just want to
12 quickly comment that I think the discussants on this
13 final point really did a great job of summing up both
14 what we understand and what we don't yet understand.
15 And with respect to the LH, we don't yet really
16 understand what the critical window is and I think that
17 is the bottom line, and whether new regulation or
18 tighter regulation needs to be imposed or suggested is
19 not sure at this point, not clear.

20 DR. STEVEN HEERINGA: Dr. McManaman?

21 DR. JAMES MCMANAMAN: Yeah, I have one
22 last comment.

23 Dr. Bailar mentioned that we should be
24 focusing on appropriate doses or physiological doses
25 and physiological outcomes.



1 Since we don't know the physiological
2 outcomes yet, I emphasize that we need more study
3 because I think we may be looking at the LH and it may
4 not be the appropriate physiological outcome, because
5 physiological doses, the concentrations that we're
6 looking at as we're focusing on atrazine not as
7 metabolites; metabolites have a lot longer life than
8 the atrazine itself.

9 So again, I think that we should be
10 focusing on, as Dr. Bailar suggested, on the
11 appropriate compounds and we don't know what those
12 appropriate compounds are yet.

13 **DR. STEVEN HEERINGA:** Dr. Horseman?

14 **DR. NELSON HORSEMAN:** I have nothing to
15 add; just thank the EPA for the quality of material
16 that we were given, and the Panel for everything I've
17 learned, and Steve for doing such a good job of keeping
18 the meeting on task.

19 **DR. STEVEN HEERINGA:** Dr. Mumtaz.

20 **DR. MOIZ MUMTAZ:** I agree with Dr. Lee
21 and Dr. Krishnan, based on the current knowledge that
22 we probably need not monitor more often than we are
23 currently monitoring. But while monitoring for
24 atrazine, I would like to see the analysis extended to
25 other chemicals present in samples so that we have a



1 better profile of the mixtures of atrazine, of course,
2 within the environment.

3 Also that would help us educate people
4 in terms of bio-availability of what is there. Always
5 when I go to the meetings when I'm in a tight spot
6 trying to explain the Committee, I use the zoo example:
7 that we go to the zoo, we go with our parents, our
8 children and everybody and have fun. There's no
9 problem, even though there are dangerous animals there.
10 But we know we'll not get exposed to unless it's
11 California or...

12 The same thing is true with chemicals:
13 just because they're there, we don't have to really
14 worry about them. What we need to do is see if they
15 are presenting in a completed exposure pathway, which
16 is from the source to the sensitive population.

17 So when we are looking at these samples,
18 if we do a better analysis, I know it will add to the
19 money; but instead of increasing the frequency, do a
20 total job with the sample I think will give a better
21 categorization of risk.

22 The same argument I do with CDC all the
23 time that is in this data they have the 160 chemicals
24 present in my body; but I want to know which of those
25 are present in a given sample so that we can figure out



1 what are the common mixes where it's potent. And it's
2 a bigger problem than I think, but I still want to make
3 that point.

4 Thank you very much. I enjoyed the
5 participation on this Panel.

6 **DR. STEVEN HEERINGA:** Thank you, Dr.
7 Mumtaz.

8 Dr. Krishnan?

9 **DR. KANNAN KRISHNAN:** You woke up in the
10 middle of the night, but I couldn't sleep.

11 I had to talk to the endocrinologists
12 before I could go to bed.

13 You know what I mean? Who wants to talk
14 about the BMR or the benchmark response that we talked
15 about the last afternoon? So I'll just make a couple
16 of comments in closing.

17 And the one paper clearly makes a case
18 for the use of the data on the attenuation of LH,
19 despite the caveats we heard. I don't see it as a
20 NOAEL or NOAEL as the white paper sees it. Rather, I
21 see it as a no observable adverse perturbation level,
22 NOAPL.

23 That's how I present the NAS work to my
24 students, because it's basically no observable adverse
25 perturbation level. It's not a no-effect level,



1 because, you know, you can really get to the
2 terminologies.

3 But in any case, the Agency here used a
4 one deviation, or standard deviation, from the control.
5 That's how the BMR was defined, and we had some
6 discussions around it.

7 I know it's the Agency policy to use 1SD
8 when a biologically significant deviation of change
9 cannot be defined or clearly defined, and I think the
10 document brings that out. But I still continue to ask
11 myself whether some of the additional data could be
12 analyzed to characterize the spread in the controls at
13 18 hours --

14 I underlined even in my notebook 18
15 hours -- maybe more than one study to provide further
16 support to the use of 1SD, or better define or provide
17 better support to the BMR, because especially when
18 we're using perturbation levels to define the benchmark
19 doses, I think it is important to analyze it in that
20 sense. So I just needed that.

21 **DR. STEVEN HEERINGA:** Thank you, Dr.
22 Krishnan.

23 Dr. Greenwood?

24 **DR. RICHARD GREENWOOD:** I think I've
25 said more than enough, thank you.



1 **DR. STEVEN HEERINGA:** We appreciated
2 your comments.

3 Dr. Schlenk.

4 **DR. DANIEL SCHLENK:** Nothing to add.

5 **DR. STEVEN HEERINGA:** Dr. Portier?

6 **DR. KENNETH PORTIER:** Nothing.

7 **DR. STEVEN HEERINGA:** Dr. Chambers?

8 **DR. JANICE CHAMBERS:** Nothing to add.

9 **DR. STEVEN HEERINGA:** Dr. Pope?

10 Dr. Bucher, you have to say something
11 since this is probably your last 10 minutes on the
12 Panel.

13 **DR. JOHN BUCHER:** I will. I want to
14 thank the Agency. This four years on this Panel has
15 been very entertaining in many cases and very
16 educational, and I appreciate the opportunity to serve.

17 I compliment the Agency with the
18 atrazine review as tackling one of the most difficult
19 scientific, social and political topics that you could
20 take on. Six meetings may be, five meetings may be too
21 many; but, you know, that's up to you.

22 And finally I want to thank Steve and
23 the rest of the permanent Panel members for a very
24 enjoyable couple of years, and thanks very much to Joe
25 Bailey for reminding me that when he asks which



1 questions you want to respond to, you really should
2 respond to him instead of just getting stuck with the
3 last one as I have been, but, thank you very much.

4 **DR. STEVEN HEERINGA:** Well, thank you
5 very much, John. As we said in our little ceremony the
6 other day that I think all of us greatly appreciate
7 your participation on this Panel, and I know personally
8 I've turned to your expertise and your sort of
9 knowledge of not only the field but also all of the
10 players in the field. It's very, very, been very, very
11 helpful and beneficial to this Panel, and I wish you
12 all the best.

13 **DR. JOHN BUCHER:** Thank you very much.

14 **DR. STEVEN HEERINGA:** Okay. At this
15 point, I'm going to turn back to Dr. Lowit, Dr. Levine
16 for any .

17 **DR. ANNA LOWIT:** Now we want to express
18 our appreciation to absolutely every single one of you.
19 As you can see, we have a difficult task and some very
20 difficult issues, and I'm amazed every time I attend
21 one of these meetings how insightful a group of
22 scientists can be when you get together; there's always
23 a synergy around it, and it's quite an amazing process.

24 This one is no different. I appreciate
25 that it takes an enormous amount of effort out of your



1 personal life and your professional life to read almost
2 700 pages of material, and thousands if you looked at
3 actually some of the raw studies. So this, we really
4 truly appreciate it, and it helps the process and helps
5 the science, and we're going to continue to inch our
6 way one step at a time forward.

7 Thank you to Dr. Bucher for your
8 service.

9 Dr. Joe Bailey and Laura Bailey and the
10 entire CP staff, another phenomenal meeting. Thank you
11 so much for your effort.

12 My personal thanks to the team, and Dr.
13 Mendez for sharing my appreciation for the team. It's
14 an amazing group of people who have done some also
15 another situation you get synergy of dedicated talented
16 people, and it's pretty amazing what you can do.

17 With that, I think that's all.

18 **DR. STEVEN HEERINGA:** Well, thank you
19 very much, Dr. Lowit. And I want to express my
20 appreciation to all the members of the Panel. It's
21 obviously a busy time of year for many of us, and to be
22 able to gather here with so much expertise, as I say, I
23 learn a tremendous amount every time I attend one of
24 these meetings and I appreciate the expertise and the
25 way that you were able to focus it during this meeting.



1 So the EPA Staff, again, just to
2 reiterate the other comments from Panel members, the
3 quality of the materials and the way it was organized,
4 the sheer volume of material, I know we often get it on
5 a short order; but you have to make it as current as
6 you possibly can, and as we've seen from your work and
7 the public commenters' work, people are working up
8 right to the last moment often on many of these
9 meetings.

10 And so that's all very much appreciated
11 in the way that you presented it and organized it for
12 this Panel, I'll just say thank you.

13 At this point, I turn to our Designated
14 Federal Official, Joe Bailey, for comments on what will
15 happen after this meeting is closed.

16 **DR. JOSEPH BAILEY:** Thanks, Dr.
17 Heeringa.

18 I want to return some thanks back to
19 Anna Lowit and her colleagues on bearing with me trying
20 to plan the meeting and get everything pulled together.
21 I think it turned out very successful.

22 I want to thank the public commenters
23 for bringing forward their helpful, informative
24 information.

25 I want to thank Dr. Portier and Dr.



1 Heeringa for chairing the meeting and keeping us on
2 track and actually getting us ahead of time. I thought
3 we were going to be here 'til mid-afternoon, at least.

4 And last but not least, I certainly want
5 to thank each of the Panel members for working with me
6 and agreeing to serve on the Panel. I really
7 appreciate it, I think a lot of good information has
8 come forward for the Agency to consider.

9 I will wish Dr. Bucher the best of luck
10 with his post-SAP endeavors.

11 And the Panel, I'll be working with you
12 over the next couple of months to get the meeting
13 minutes finalized, and those will be done within the
14 usual 90-day period. Once they're completed, they'll
15 be available on the website and in the public docket.
16 So, thank you all.

17 **SPEAKER:** Timeline for everybody to get
18 the first draft?

19 **DR. JOSEPH BAILEY:** Well

20 **DR. STEVEN HEERINGA:** We'll have a break
21 in our meeting in just a moment.

22 **SPEAKER:** Okay. I didn't want to
23 forget.

24 **DR. STEVEN HEERINGA:** Again, all the
25 materials that were presented before the Panel in hard



1 copy or electronic should be available on the docket
2 within a reasonable period of time here.

3 And again, thank you to everybody who
4 participated in this process, the EPA Scientific Staff
5 and public commenters who worked with us on Wednesday
6 and everything that they contributed to this process.
7 And with that, I'll call this meeting to a close.

8 Permanent Panel or Panel members, if we
9 could meet in our breakout room to plan the
10 organization of our first draft and the timeline for
11 that.

12 So, thank you everybody; have a good
13 day.

14 (WHEREUPON, the meeting was concluded 10:17 a.m.)
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CAPTION

The foregoing matter was taken on the date, and at the time and place set out on the Title page hereof.

It was requested that the matter be taken by the reporter and that the same be reduced to typewritten form.

Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.



1 CERTIFICATE OF REPORTER

2 COMMONWEALTH OF VIRGINIA

3 AT LARGE:

4 I do hereby certify that the witness in the foregoing
5 transcript was taken on the date, and at the time and
6 place set out on the Title page hereof by me after
7 first being duly sworn to testify the truth, the whole
8 truth, and nothing but the truth; and that the said
9 matter was recorded stenographically and mechanically
10 by me and then reduced to typewritten form under my
11 direction, and constitutes a true record of the
12 transcript as taken, all to the best of my skill and
13 ability.

14 I further certify that the inspection, reading and
15 signing of said deposition were waived by counsel for
16 the respective parties and by the witness.

17 I certify that I am not a relative or employee of
18 either counsel, and that I am in no way interested
19 financially, directly or indirectly, in this action.

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22
23
24 MARK REIF, COURT REPORTER / NOTARY

25 SUBMITTED ON SEPTEMBER 17, 2010



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